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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/644,577	08/20/2003	Connie Sanchez	05432/100M919-US2	5196

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EXAMINER	
CHONG, YONG SOO	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 09/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/644,577	SANCHEZ ET AL.	
	Examiner	Art Unit	
	Yong S. Chong	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/10/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

This Office Action is in response to applicant's arguments filed on 8/7/2006. Claim(s) 38 has been added. Claim(s) 20-38 are pending. Claim(s) 20 has been amended. Claim(s) 20-38 are examined herein. Applicant's amendments have rendered the rejections in the previous Office Action moot and are therefore withdrawn. The following new rejections will now apply.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 20-38 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 of copending Application No. 10/984,536 in view of Applicant's own admission of the prior art. A method of treating premenstrual syndrome with escitalopram is disclosed. Although escitalopram is not disclosed to be the sole active ingredient, no other ingredients are disclosed. Therefore, it would be obvious to utilize escitalopram as the sole active

ingredient. This application does not disclose a patient population who has failed to respond to initial treatment with a selective serotonin reuptake inhibitor other than escitalopram.

In applicant's own admission, the specification discloses that clinical studies on depression and anxiety disorders indicate that non-response or resistance to SSRIs, where at least 40-60% reduction in symptoms has not been achieved during the first 6 weeks of treatment (pg. 1, paragraph 3).

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to administer escitalopram to a patient who failed to respond to the initial treatment with a selective serotonin reuptake inhibitor other than escitalopram.

A person of ordinary skill in the art would have been motivated to administer escitalopram because of the reasonable expectancy of successfully optimizing a treatment for premenstrual syndrome using another selective serotonin reuptake inhibitor.

This is a provisional obviousness-type double patenting rejection.

Response to Arguments

Applicant argues that since this application is the earlier filed application and found allowable, the provisional rejection should be withdrawn. Examiner is perplexed by Applicant's interpretation of MPEP 804, especially since this application was never deemed allowable. The double patenting rejection is maintained for reasons of record.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham vs John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 20-38 are rejected under 35 U.S.C. 103(a) as being obvious over Boegesoe et al. (US Patent 4,943,590) and further in view of Norden et al. (US Patent 5,789,449), the Merck Manual (16th edition, 1992, pg. 1791), and Applicant's own admission of the prior art.

The instant claims are directed to a method of treating premenstrual syndrome by administering escitalopram to a patient who failed to respond to initial treatment with a SSRI other than escitalopram.

Boegesoe et al. discloses the method of treating depression in a patient with the (+) enantiomeric form of citalopram, otherwise referred to as escitalopram (col. 1, lines 9-26), which is also disclosed to be an inhibitor of serotonin uptake. Acceptable

pharmaceutical salts of escitalopram include oxalate (col. 1, lines 29-42). The daily dosage of escitalopram is disclosed to be from 5 to 50 mg (col. 8, lines 55-60).

However, Boegesoe et al. fail to disclose specifically a method of treating premenstrual syndrome with escitalopram to a patient who failed to respond to initial treatment with a SSRI other than escitalopram.

Norden et al. teach a method of treating premenstrual syndrome by administering a serotonin reuptake inhibitor, for example citalopram, which is the racemic form of escitalopram, to a patient (col. 18, lines 36-38). Moreover, the Merck Manual teach that depression is a symptom of premenstrual syndrome (16th edition, 1992, pg. 1791).

In applicant's own admission, the specification discloses that clinical studies on depression and anxiety disorders indicate that non-response or resistance to SSRIs, where at least 40-60% reduction in symptoms has not been achieved during the first 6 weeks of treatment (pg. 1, paragraph 3).

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to administer patients suffering from premenstrual syndrome an effective amount of escitalopram, because both premenstrual syndrome and depression are treatable by inhibiting the uptake of serotonin. Treating a patient suffering from depression with escitalopram will also treat the same patient who is suffering from premenstrual syndrome.

A person of ordinary skill in the art would have been motivated to administer escitalopram to patients suffering from premenstrual syndrome, because of the

expectancy of the same amount of success when treating patients suffering from depression with escitalopram.

Response to Arguments

Applicant argues that none of the cited references disclose or suggest that escitalopram could be effective in treating PMS.

In response to applicant's arguments against the references, one cannot show nonobviousness by attacking references individually where the rejections are based on the combination of references. See *In re Keller*, 642 F. 2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F. 2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant argues that there is no motivation to administer escitalopram to treat PMS in patients who have failed to respond to initial treatments with a different SSRI. This is not persuasive because since the patient did not respond to a particular SSRI, it is obvious to one of ordinary skill to administer another SSRI with the reasonable expectation of successfully treating PMS.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong S. Chong whose telephone number is (571)-272-8513. The examiner can normally be reached on M-F, 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENI PADMANABHAN can be reached on (571)-272-0629. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

YSC

/Shengjun Wang/
SHENGJUN WANG
PRIMARY EXAMINER